Title: Recruitment for Online, Patient-Centered, Adrenal Insufficiency Study

We are looking to recruit subjects for a large cohort study of adrenal insufficiency – with a focus on symptoms, diagnosis, quality of life, and outcomes of treatment.

What:

We are starting a research project to study the range of adrenal insufficiency (AI) disease, with the goals to understand the disease(s) better, improve treatments and look for ways to predict or prevent it. The project is designed to enroll subjects online, with baseline information collected at that point and then continue to monitor people over time with a focus on how they may change and tracking events that occur such as adrenal crises. This type of study is called a longitudinal observational cohort study or research registry. The name of the study is pretty simple, AIS – the Adrenal Insufficiency Study

As you may know, adrenal insufficiency is a somewhat rare disease that is associated with the risk of developing adrenal crises if the individual is stressed and cannot respond with increased cortisol. Studies from Europe show that even well-educated and presumably careful people are vulnerable to adrenal crisis and at increased risk of dying. It is also a hard disease to manage for many people and it is not uncommon for patients to struggle with persistent symptoms. Patients need to take hydrocortisone or prednisone every day and often take other drugs to keep functioning - but taking too much can result in problematic side effects.

The United States has lagged behind many of the European countries in studying adrenal insufficiency so we actually don't have any good data on how common the disease is here, nor do we have information on how well patients are doing under the current treatment recommendations. Studies from Europe have identified increases in mortality and other problems within their populations of AI patients so it raises the question of what is happening here. The United States is much more diverse than the European countries that have reported on their situations, has a very different health care system and it is possible that we are different. So, this proposal is to begin collecting information about who has the disease, how they are being treated and how well are they doing.

Although the primary goal is to study the state of things in the United States, the registry is open to anyone who meets the inclusion criteria – even outside the US. A second priority would be North America, and so Canadians and Central Americans could be an additional focus.

Who:

A previous registry through the National Adrenal Diseases Foundation enrolled about 1400 people but they were almost all non-Hispanic white individuals. We want everyone possible who has adrenal insufficiency to enroll and we would really like to get participation from Hispanics, African Americans, Asians and the wide range of other diverse populations. There is a real risk that people who have historically had difficulty being "heard" by the medical

profession are not getting diagnosed with this disease. Unfortunately, when people are not diagnosed, they are likely to die.

We also want people who are "at-risk" of developing adrenal insufficiency. Those would be people with a family history of AI, those who have other autoimmune diseases (thyroid disease, rheumatoid arthritis, type 1 diabetes, celiac disease etc.) and possibly people with symptoms suggestive of AI who have had negative tests. People who have been taking oral glucocorticoids (steroids, like prednisone) for other diseases, are also at risk of secondary adrenal insufficiency – so we want them. We also need control or "normal" people for comparison. These people could and should be coming from the same geographic region as the AI and at-risk people. This is a great opportunity to recruit your friends or family!

So please, pass the word about this study. It would be great if we could get thousands of people signed up. There are probably 50,000 – 100,000 people in the US with some form of adrenal insufficiency. If you are a member of a minority population – tell people in your community about the study and encourage them to join.

Why:
There is a lot of work to be done in order to make life better for people with adrenal insufficiency. We need better drug treatments and blood tests that can reflect how well treatments are working. With better drugs and understanding of how to treat the disease, hopefully more people will be able to return to health and improve their quality of life. We also need to understand the mechanisms of disease, as well as the genetic and environmental risks factors. Once we understand those better, the goal needs to be prevention or reversal of the disease.

Specifics:
The inclusion criteria for this study are: age 20 and older and any kind of adrenal insufficiency – primary AI or Addison's disease, secondary or tertiary AI from changes in the pituitary or hypothalamus or brain surgery, congenital adrenal hyperplasia (CAH), and other genetic or familial disease.

AI patients who are participating in other research studies are welcome to be part of this registry – just let us know when completing the data collection about the other studies or registries you are in.

Enrollment will take about 30 minutes initially, and you need to have a working email address. If you are an AI patient we will eventually ask you for some medical records to verify your diagnosis. These are requested from you later by email.

The link to the study is through the National Adrenal Diseases Foundation (NADF)website at: https://www.nadf.us

There is detailed information about the study included in the research consent form. You can sign up to just be in the first round and we will at least be able to count you; or better yet, you can continue to be part of the study for the long haul and we will contact you by email every six months for an update on your health. You also have the option to be contacted about future research studies as we try to look at genetic factors or identify better blood tests.

Right now, the study is not formally funded. We are not looking for money to participate in it or to support research in general, but we are also not paying anyone to be in the study.

You can direct questions about the study to adrenal@NJHealth.org

The study is centered at National Jewish Health in Denver and has been reviewed by the National Jewish Institutional Review Board to ensure compliance with human subjects research regulations and data is being managed in compliance with HIPAA regulations.

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